K112963

NOV 22 2011

Section 11. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K112963

1. Submitter's Identification:

TaiDoc Technology Corporation
3F, 5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 248, Taiwan

Correspondent:
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Regulatory Affairs Specialist
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Prepared date: September 30, 2011

2. Device name:

Proprietary name: TD-4257 Blood Glucose Monitoring System and TD-4257 Multi Blood Glucose Monitoring System

Regulatory information:

A. Regulation section: 21 CFR 862.1345 Glucose Test System
B. Classification: Class II
C. Product Code: LFR, Glucose Dehydrogenase, Glucose
NBW, System, Test, Blood Glucose, Over The Counter
D. Panel: Clinical Chemistry (75)

3. Intended Use:

For single use device

The TD-4257 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.

The TD-4257 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates.

The TD-4257 Blood Glucose Test Strips are for use with the TD-4257 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

For multiple patient use device

The TD-4257 Multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary, venous and neonatal whole blood samples. The TD-4257 Multi Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple patient use in professional healthcare settings as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus.

Professionals may test with capillary, venous and neonatal whole blood. Capillary samples may be drawn from the fingertip, and in the case of neonates, from the heel.

The system is only used with single-use, auto-disabling lancing devices.

The TD-4257 Multi Blood Glucose Test Strips are for use with the TD-4257 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary, venous and neonatal whole blood samples.

4. Device Description:

   The system consists of three main products: the meter, test strips, and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results.

5. Substantial Equivalence Information:

A. Predicate device name: TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System

B. Predicate K number: K101635

C. Comparison with predicate:

The modified TD-4257 Blood Glucose Monitoring System and TD-4257 Multi Blood Glucose Monitoring System have the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- Modification in the physical appearance
- Minor software modifications of the glucose meter
- Change of the data transmission method from RS-232 to Bluetooth
- Labeling change due to the above modifications

6. Test Principle:
The detection and measurement of glucose in blood is by an electrochemical biosensor technology using glucose dehydrogenase.

7. Performance Characteristics:
TD-4257 Blood Glucose Monitoring System/TD-4257 Multi Blood Glucose Monitoring System has the same performance characteristics as the predicate device.

A comparison of system accuracy performance demonstrated that the TD-4257 Blood Glucose Monitoring System/TD-4257 Multi Blood Glucose Monitoring System and the TD-4239 Blood Glucose Monitoring System/TD-4239 Multi Blood Glucose Monitoring System are substantially equivalent.

Software verification and validation testing confirmed that the performance, safety and effectiveness of the TD-4257 Blood Glucose Monitoring System /TD-4257 Multi Blood Glucose Monitoring System are equivalent to the predicate device.

8. Conclusion:

Based on the information provided in this submission, the TD-4257 Blood Glucose Monitoring System and TD-4257 Multi Blood Glucose Monitoring System are substantially equivalent to the predicate TD-4239 Blood Glucose Monitoring System and TD-4239 Multi Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

NOV 2 2 2011

Taidoc Technology Corporation
c/o Teling Hsu
3f, 5f, No.127 Wugong 2nd Rd,
Wugu District
New Taipei City, Taiwan 24888

Re: K112963
Trade name: TD-4257 Blood Glucose Monitoring System
TD-4257 Multi Blood Glucose Monitoring System
Regulation Number: 21CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: NBW, LFR
Dated: September 30, 2011
Received: October 5, 2011

Dear Ms. Hsu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Section 8.

Indications for Use

510(k) Number (if known): K112963

Device Name: TD-4257 Blood Glucose Monitoring System, model TD-4257

Indications for Use:

The TD-4257 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood samples from the finger. It is intended to be used by a single person and should not be shared.

The TD-4257 Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus or be used on neonates.

The TD-4257 Blood Glucose Test Strips are for use with the TD-4257 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K112963

Indications for Use

510(k) Number (if known): K112963

Device Name: TD-4257 Multi Blood Glucose Monitoring System, model TD-4257

Indications for Use:

The TD-4257 Multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary, venous and neonatal whole blood samples. The TD-4257 Multi Blood Glucose Monitoring System is intended for testing outside the body (*in vitro* diagnostic use) and is intended for multiple patient use in professional healthcare settings as an aid in monitoring the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus.

Professionals may test with capillary, venous and neonatal whole blood. Capillary samples may be drawn from the fingertip, and in the case of neonates, from the heel.

The system is only used with single-use, auto-disabling lancing devices.

The TD-4257 Multi Blood Glucose Test Strips are for use with the TD-4257 Multi Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary, venous and neonatal whole blood samples.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

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